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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,665	09/21/2006	Reiko Irie	14875-155US1 C1-A0223P-US	1468
26161 7590 04/20/2009 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER OUSPENSKI, ILIA I	
			ART UNIT 1644	PAPER NUMBER
			NOTIFICATION DATE 04/20/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,665	<b>Applicant(s)</b> IRIE ET AL.	
	<b>Examiner</b> ILIA OUSPENSKI	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-14, 16-34, 36, 38-40 and 48-69 is/are pending in the application.
- 4a) Of the above claim(s) 4, 10, 16-18, 21, 23, 26-33, 36, 38-40, 48-65, 68 and 69 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-9, 11-14, 19, 20, 22, 24, 25, 66 and 67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/21/2006; 07/18/2007; 09/17/2007; 11/25/2008</u> . | 6) <input type="checkbox"/> Other: _____  |



## **DETAILED ACTION**

1. Applicant's remarks filed on 01/09/2009 are acknowledged.

2. Claims 1, 3-14, 16-34, 36, 38-40 and 48-69 are pending.

Claims 26 – 33, 36, 38 – 40, 48 – 65, and 68 – 69 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 08/08/2008.

Applicant's election without traverse of the Species wherein the vector does not comprise a nucleotide sequence encoding an IgM J chain, in the reply filed on 01/09/2009 is acknowledged.

Claims 4, 10, 16 – 18, 21 and 23 are presently withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected Species, pursuant to Applicant's elections made on 08/08/2008 and 01/09/2009, there being no allowable generic or linking claim.

Claims 1, 3, 5-9, 11-14, 19-20, 22, 24-25, 34, 66 and 67 are presently under consideration.

3. The following is a quotation of the **second paragraph of 35 U.S.C. 112**.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

4. Claim 9 is rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite in the recitation of “the genes (1) and (2),” because the recitation lacks proper antecedent basis in the clauses (1) and (2), which do not recite “genes.” Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

5. The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

6. Claims 1, 3, 5 – 8, and 24 – 25 are rejected under **35 U.S.C. 112, first paragraph**, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of the generically recited "transformed cell" in the absence of a recitation specifying what the cell has been transformed with.

One of skill in the art is aware that a cell may be transformed by a great variety of nucleic acid molecules which are different in their structures and functions. In the absence of a disclosure in the instant specification of sufficiently detailed, relevant identifying characteristics, such as complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics, the skilled artisan cannot envision all the contemplated "transformed cells" encompassed by the instant claims.

Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993). The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, §1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The

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specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, January 5, 2001.

7. The following is a quotation of the appropriate paragraphs of **35 U.S.C. 102** that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

8. Claims 9, 11, 14, 19, and 66 – 67 are rejected under **35 U.S.C. 102(b)** as being anticipated by Cattaneo et al. (WO 89/01975; of record – cited on IDS of 09/17/2007; see entire document).

Cattaneo et al. teach an expression vector comprising nucleotide sequences encoding IgM H and L chains, wherein IgM expression is controlled by transcriptional regulatory sequences (see entire document, in particular e.g. Figures 1 and 2). Cattaneo et al. further teach cells transformed by the vector and IgM production by these cells (e.g. Table 1 at page 14). Cattaneo et al. teach that the IgM secreted by glioma transfectants contains pentamers and hexamers in approximately equal amounts (page 21).

Therefore, the teachings of the reference anticipate the instant claimed invention.

9. Claim 1, 3, 5 – 6, 9, 11, 14, 19 – 20, 22, 24 – 25, and 66 – 67 are rejected under **35 U.S.C. 102(b)** as being anticipated by Green (J. Immun. Methods, 1999, 231: 11 – 23; see entire document).

Green teaches that by 1999, XenoMouse™ technology was widely used for production of human antibodies (e.g. the Abstract). XenoMouse™ technology includes introduction of genes encoding human antibody heavy and light chains, including IgM (e.g. page 13), into the mouse genome. IgM is expressed at levels of 700 µg/ml (i.e. 700 mg/L) in mouse serum (e.g. page 16). As such, cells of XenoMouse™ are within the scope of the instant claims, because they are “transfected” and produce the recited level of IgM. XenoMouse™ technology further includes generation of hybridomas (e.g. page 18), i.e. established cell lines. Cells of XenoMouse™ comprise an expression vector comprising nucleotide sequences encoding IgM H and L chains controlled by transcriptional regulatory sequences. Since XenoMouse™ cells are structurally the same as instantly claimed, their functional properties are inherently the same as instantly recited, including the ratio of hexameric form of IgM among total IgM expressed.

Therefore, the teachings of the reference anticipate the instant claimed invention.

10. Claims 1, 3, 5 – 9, 11 – 14, 19 – 20, 22, 24 – 25 and 66 – 67 are rejected under **35 U.S.C. 102(b)** as being anticipated by Wood et al. (J. Immunol., 1990, 145: 3011 – 3016; of record – cited on IDS of 07/18/2007; see entire document).



Wood et al. teach expression of IgM in CHO cells under the control of SV40 early promoter and adenovirus major late promoter (see entire document, in particular e.g. page 3012, paragraph bridging first and second columns). Wood et al. teach a level of expression of  $68.6 \mu\text{g}/10^6 \text{ cells}/48 \text{ h}$  (e.g. Table 1, last line), i.e.  $34.3 \text{ pg}/\text{cell}/\text{day}$ . This value is so close to the instantly recited  $35 \text{ pg}/\text{cell}/\text{day}$  that one of skill in the art would understand that the difference is not meaningful.

Since the IgM-expressing cells of Wood et al. are structurally the same as instantly claimed, their functional properties are inherently the same as instantly recited, including the ratio of hexameric form of IgM among total IgM expressed.

Therefore, the teachings of the reference anticipate the instant claimed invention.

**11. Claim 34 is allowable.**

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is (571)272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ILIA OUSPENSKI/

ILIA OUSPENSKI, Ph.D.

Primary Examiner

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April 7, 2009